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YABUT, DIANE D				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/554,964

Applicant(s)

DORN, JURGEN

Examiner

DIANE YABUT

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7, 8 and 10-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 8 and 10-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to applicant's pre-appeal brief received on 11/12/2007.

The Final Rejection dated 08/15/2007 has been withdrawn and prosecution has been re-opened.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 7, 8, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 7, 8, and 15 are dependent upon cancelled claim 6. As such, these claims have not been further treated on the merits thereof.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-5, 10-14, and 16-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Helgerson** (U.S. Patent No. **5,695,499**) in view of **Hancock** (U.S. Patent No. **6,702,802**) and **Wijay** (U.S. Patent No. **5,690,643**).

Claims 1-5, 10-14, 16-18, 20-28: Helgerson discloses an inner catheter including a wire coil **32**, the wire coil having an outer tube or lubricious coating or fluid disposed around at least the intermediate region ("covering," see col. 4, lines 61-67), a thermoplastic elastomeric sheath **50** disposed around at least a portion of the inner catheter and having a silicone material disposed between the outer tube and sheath (col. 5, line 66 to col. 6, line 5), the sheath being retractable in a proximal direction relative to the inner catheter (col. 7, lines 1-3, Figures 4-8). An atraumatic tapered tip **31** is positioned at the distal end of the catheter, the tip being formed as part of the sheath and the sheath being connected to the inner catheter (Figure 2). Helgerson also discloses a medical device or self-expanding stent **10** (col. 3, line 67) being maintained in position between the sheath and the inner catheter, the medical device being radially compressed and subsequently releasable by retraction of the sheath in a proximal direction relative to the inner catheter, and an actuation device **60** connected to a proximal end of the inner catheter and the sheath, configured to retract the sheath in a proximal direction relative to the inner catheter (Figures 2 and 6-8, col. 6, line 62 to col. 7, line 16).

Although Helgerson acknowledges that the wire coil **32** has closely spaced coils (col. 4, lines 14-17) or may have spaces that exist between some of the coils (col. 4, lines 35-38), it is not expressly disclosed to have a closed-coil structure at an intermediate region of the wire coil and an open-coil structure at proximal and distal regions of the wire coil.

Hancock teaches a catheter with a wire coil having a closed-coil structure at an intermediate region **279** and an open-coil structure at proximal and distal **277** regions (see Figure 16). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a closed-coil structure at an intermediate region and an open-coil structure at proximal and distal regions of the inner catheter, as taught by Hancock, to Helgerson in order to facilitate delivery of the device through the body and to provide a gradual change in stiffness when moving from region to the other (col. 14, lines 53-67).

Helgerson also does not disclose the wire coil being disposed around an inner tube.

Wijay teaches a stent delivery system comprising an open coil **36** surrounding an inner tube **19** defining a guide wire lumen and a medical-device-receiving annulus around a distal portion, the coil defining a liquid flow path from the proximal end to the distal end of a catheter including a radially-extending portion through the open-coil structure and an annular flow path bounded by the inner tube and the wire coil, in order to permit perfusion to the device so that drugs or blood or other fluid can be carried through the device which may reduce patient discomfort (Figure 5, col. 2, lines 15-36, col. 4, lines 1-11 and 37-42). It would have been obvious to one of ordinary skill in the art at the time of invention to provide an open-coil structure, as taught by Wijay, to Helgerson in order to permit perfusion and reduce patient discomfort.

Claim 19: Helgerson discloses a flexible tip **31** (col. 5, lines 20-29), although does not expressly disclose that it be formed of polyurethane. It would have been obvious to one of ordinary skill in the art at the time of invention to have the tip be made of

polyurethane material, since it was well known in the art as a suitable biocompatible polymer.

5. Claims 29-32 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Helgerson** (U.S. Patent No. **5,695,499**) in view of **Hancock** (U.S. Patent No. **6,702,802**) and **Wijay** (U.S. Patent No. **5,690,643**), as applied to claim 24 above, and further in view of **Dwyer** (U.S. Pub. No. **20020016597**).

Claims 29-32: Helgerson, Hancock, and Wijay disclose the claimed device, except for a pusher element and a push rod disposed about the inner tube at a proximal region thereof, a distal end of the push rod joined to a proximal end of the wire coil.

Dwyer teaches a distal end of the wire coil being joined to a pusher element **40** disposed about a distal region of the inner tube that includes a shoulder, and a stent bed **42** being defined along a distal region of the inner tube between the shoulder and a distal end of the inner tube (Figure 2, page 6, paragraph 50) and a push rod disposed about the inner tube at a proximal region thereof, a distal end of the push rod joined to a proximal end of the wire coil (page 1, paragraph 8; page 2, paragraph 13). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a pusher element or push rod, as taught by Dwyer, to Helgerson, Hancock, and Wijay since it was well known in the art to efficiently advance a stent with a pusher in cooperation with a retraction sheath.

Claims 34-36: Helgerson, Hancock, and Wijay disclose the claimed device, except for the actuating device including a first member connected to the inner catheter and a

second member connected to the sheath, the second member including a locking member configured to prevent relative movement between the inner catheter and the sheath.

Dwyer teaches an actuating device **58** including a first member connected to the inner catheter and a second member connected to the sheath, the second member including a locking member configured to prevent relative movement between the inner catheter and the sheath (page 6, paragraphs 49-50). An open position of the actuating device includes the first member spaced apart from the second member and wherein a closed position of the actuation device includes the first member adjacent to the second member (page 6, paragraphs 49-50). The second member includes a luer member in fluid communication with the inner catheter (page 6, paragraphs 49-50). It would have been obvious to one of ordinary skill in the art at the time of invention to provide first and second members in the actuating device, as taught by Dwyer, to Helgerson, Hancock, and Wijay in order to prevent inadvertent deployment of the stent.

6. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Helgerson** (U.S. Patent No. **5,695,499**) in view of **Hancock** (U.S. Patent No. **6,702,802**) and **Wijay** (U.S. Patent No. **5,690,643**), as applied to Claim 24 above, and further in view of **Klemm** (U.S. Patent No. **5,458,615**).

Claim 33: Helgerson, Hancock, and Wijay disclose the claimed device, except for a radiopaque marker band being attached to an inner surface of a distal end of the

sheath, although Helgerson does disclose radiopaque markers **36** and **37** disposed on the coil (Figure 4).

Klemm teaches a radiopaque marker band being attached to an inner surface of a distal end of a sheath so that the physician can determine when the sheath has been withdrawn a sufficient distance so as not to interfere with the deployment of the stent (col. 9, lines 25-35). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a radiopaque marker on the sheath, as taught by Klemm, to Helgerson, Hancock, and Wijay in order to avoid interference with the deployment of the stent.

Response to Arguments

7. Applicant's arguments with respect to claims 1-5, 7-8, and 10-36 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731